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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,151	04/16/2002	Takashi Shigematsu	13723-002001	8643
26161 7590 02/09/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER LUM, LEON YUN BON	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 02/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/009,151

Applicant(s)

SHIGEMATSU ET AL.

Examiner

Leon Y. Lum

Art Unit

1641

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**LONG V. LE**  
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Continuation of 11. does NOT place the application in condition for allowance because of the reasons set forth in the previous Office Action. The response After Final filed on January 12, 2007 did not include claim amendments, but provided arguments traversing the rejections made in the previous Office Action. Specifically, Applicants argue several points:

(1) Applicants contend that the combination of Proksch (US 4,216,117) with each of Kamarei (US 4,217,117) and Magneson (US 5,547,873) does not teach the claimed invention because Proksch teaches determining amounts of cholesterol and triglyceride, and such compounds are not lipoproteins. See page 10, 3<sup>rd</sup>-4<sup>th</sup> paragraphs and page 13, 5<sup>th</sup> full paragraph.

(2) Applicants argue that the Examiner is "picking and choosing" the freeze-thaw treatment and freeze-drying steps out of a "laundry list" of 26 disclosed steps. See pages 10-13, especially page 12, 2<sup>nd</sup> paragraph.

(3) Applicants argue that since Magneson discloses that the proteins are recovered in their native structures, they cannot teach the denatured proteins of the claimed invention. See page 14, the entire page.

Applicants' arguments have been fully considered, but are not convincing and do not overcome the applied rejections.

Regarding Applicants' argument (1) above, Proksch teaches a lipoprotein diluent having lipoproteins therein. While Applicants correctly point out that Proksch explicitly describes the measurement of cholesterol and triglyceride, it is noted that these compounds make up the lipid portion of lipoproteins, which are protein-lipid compounds. Therefore, by detecting the "part" of cholesterol and triglyceride, the "whole" of lipoproteins are necessarily detected.

Regarding Applicant's argument (2) above, Applicants cite *In re Fine*, 5 USPQ 2d 1596-1600 (Fed. Cir. 1988) in supporting their claim that the Examiner was "picking and choosing." The specific portion of the case cited is the phrase "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosure in the prior art to deprecate the claimed invention." See page 12, 2<sup>nd</sup> full paragraph of the Arguments. *In re Fine* was a decision rendered by the Court of Appeals for the Federal Circuit which held that the Examiner's application of an obvious rejection was improper because there was no explicit reason to combine the primary and secondary references, other than an "obvious to try" rationale. *Id.* at 1600. The court concluded that the Examiner had engaged in improper hindsight reconstruction by "picking and choosing" an isolated secondary reference to teach a limitation the primary reference was lacking. *Id.* The case therefore hinged on the fact that the "picking and choosing" was performed in the entire prior art to select one reference to combine with another reference. However, Applicants' case here is different and distinguished from *In re Fine*. The two steps in question, the "freeze-thaw treatment" and "freeze-drying," were not in separate references, but disclosed in one reference (i.e. Kamarei). Furthermore, in the same paragraph in which Kamarei discloses the two freezing steps, Kamarei also explicitly teaches that "any combination of more than one of the above methods" is applicable. See Kamarei, column 8, lines 51-52. Therefore, Kamarei explicitly teaches that the freeze-drying and freeze-thaw treatment can be combined to produce one method with two freezing steps in succession. Although the two freezing steps are among a plurality of different treatments that can be chosen in combination, the mere fact that there is a plurality of steps to choose from does not implicate improper hindsight, especially since the reference itself discloses that different treatment methods can be combined. Applicants have also traversed the Examiner's conclusion that in combining the freeze-thaw and freeze-drying steps, that the freeze-drying must be performed after the freeze-thaw treatment. Applicants argue that it would be possible to dissolve the freeze-dried products in order to perform a freeze-thaw treatment. However, this assumption requires that such a dissolving step be inserted. Such a step is not cited in the rejection, which relies on Kamarei for just the freeze-thaw and freeze-drying treatments. Therefore, in combining these steps, it would be necessary to perform the freeze-thaw treatment first, since the freeze-drying step removes all liquid and would therefore prevent subsequent freeze-thawing.

Regarding Applicants' argument (3) above, the patentable weight of the instant claims is the active method steps claimed. Since Magneson teaches the same steps, as described in the previous Office Action, the claims are taught in the prior art. Since the instant claims having open language (i.e. "comprising"), they leave open the ability for a prior art reference to teach the claimed language even if it includes additional steps not recited by the instant claims. Therefore, although Magneson teaches reconstituted proteins that retain their native structure, this does not per se negate the reference's application against the instant claims of a denatured protein structure due to (1) the open "comprising" language and (2) the fact that Magneson teaches each and every claimed step.



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